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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,605	12/31/2001	George A. O'Toole	00246-266US1	1939
26161	7590	11/24/2003		EXAMINER
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110				FORD, VANESSA L
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/24/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Docketed By Practice Systems
Action Code: <u>RESPONSE LM</u>
Base Date: <u>11-24-03</u>
Due Date:
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Initials: <u>OAT</u>

Docketed By Billing Secretary
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Deadline:
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WASHINGTON, DC 20231
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Paper No.

15

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment filed on 12/27/03 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on September 8, 2000 (see 65 Fed. Reg. 54603, Sept. 8, 2000, and 1238 O.G. 77, Sept. 19, 2000). In order for the amendment to be compliant, applicant must supply the following omissions or corrections in response to this notice.

THE FOLLOWING ITEMS ARE REQUIRED FOR COMPLIANCE WITH RULE 1.121 (APPLICANT NEED NOT RESUBMIT THE ENTIRE AMENDMENT):

- 1. A clean version of the replacement paragraph(s)/section(s) is required. See 37 CFR 1.121(b)(1)(ii).
- 2. A marked-up version of the replacement paragraph(s)/section(s) is required. See 37 CFR 1.121(b)(1)(iii).
- 3. A clean version of the amended claim(s) is required. See 37 CFR 1.121(c)(1)(i).
- 4. A marked-up version of the amended claim(s) is required. See 37 CFR 1.121(c)(1)(ii).

Explanation: _____

(LIE: Please provide specific details for correction to assist the applicant. For example, "the clean version of claim 6 is missing.")

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/dcom/olia/pbg/sampleaf.pdf>. A condensed version of a sample amendment format is attached.

- PRELIMINARY AMENDMENT:** Unless applicant supplies the omission or correction to the preliminary amendment in compliance with revised 37 CFR 1.121 noted above within ONE MONTH of the mail date of this letter, examination on the merits may commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.
- AMENDMENT AFTER NON-FINAL ACTION:** Since the above-mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of ONE MONTH or THIRTY DAYS from the mailing of this notice, whichever is longer, within which to supply the omission or correction noted above in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Legal Instruments Examiner (LIE)

(Rev. 12/01)

ATTACHMENT:

SAMPLE AMENDMENT FORMAT

Conventional Heading Information
for Amendment Supplied Here (Applicant, Appl. No., etc)

AMENDMENT

Sir:

In response to the Office action of October 10, 2000, please amend the above-identified application as follows:

In the Specification:

Please replace the paragraph beginning at page 5, line 15, with the following rewritten paragraph:

-- In this construction the electric heating elements are positioned directly beneath the iron grid bars and melted fat is carried off in grooves formed in the upper surfaces of the bars. --

In the claims:

Please cancel claim 6.

Please amend claim 7 as follows:

7. (Amended) A griller as claimed in claim 1 wherein the power consumption of the heater element is 1250 watts and the weight of the grill member is about 3.5 kg.

(Page Break)

REMARKS/ARGUMENTS

Claims 1-5 and 7-10 remain in this application. Claim 6 has been canceled. Claim 7 has been amended.

Claims.....

.....
Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

SIGNATURE _____

(Page Break)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

Paragraph beginning at line 15 of page 5 has been amended as follows:

In this construction the electric heating elements are positioned directly beneath the iron grid bars and melted fat is carried off in grooves formed in the upper surfaces of the bars.

In the claims:

Claim 6 has been canceled.

Claim 7 has been amended as follows:

7. (Amended) A griller as claimed in claim 1 wherein the power consumption of the heater element is 1250 +600 watts and the weight of the grill member is about 3.5 kg.

****PROSECUTION****PATENT
ATTORNEY DOCKET NUMBER: 00246/505003

The U.S. PTO date stamp sets forth the date of receipt of:

Applicant/Patentee: George O'Toole et al.Serial/Patent Number: 09/673,605Filed/Issued: October 17, 2000Title: REGULATION OF BIOFILM FORMATION

<input type="checkbox"/> Transmittal Letter	Pages: _____	<input type="checkbox"/> Declaration & POA	Pages: _____
<input type="checkbox"/> Notice of Missing Parts	Pages: _____	<input type="checkbox"/> Assignment & Cover Sheet	Pages: _____
<input type="checkbox"/> Reply to Missing Parts	Pages: _____	<input type="checkbox"/> Change of Address	Pages: _____
<input type="checkbox"/> Reply to Examiner's Action	Pages: _____	<input type="checkbox"/> Small Entity Statement	Pages: _____
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<input checked="" type="checkbox"/> Check	\$: <u>332.00</u>	<input type="checkbox"/> Other _____	Pages: _____

 Other Preliminary Amendment Pages: 6Atty/Secy: KBB/SJE Client/Matter Name: Harvard/Biofilm U.S. Natl. Date: 12/20/00
(smb)**COPY**



PATENT
ATTORNEY DOCKET NO. 00246/505003

Certificate of Mailing: Date of Deposit: December 20, 2000

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan M. Barry
Printed name of person mailing correspondence

Susan M. Barry
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: George O'Toole et al.

Art Unit: Not yet Assigned

Serial No.: 09/673,605

Examiner: Not yet Assigned

Filed: October 17, 2000

Title: REGULATION OF BIOFILM FORMATION

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Kindly amend the application as follows.

In the Claims:

COPY

Please amend claims 23, 36, and 38 as follows.

23. (Amended) The method of claim 40 [22], wherein *sad* polypeptide is encoded by a *Pseudomonas fluorescens* *sad* gene.

36. (Amended) The method of claim 34, wherein at least 5% [,10%, 25%, 50%,

75%, or 100%] of the bacterial cells contacted by the bacterial growth medium in said culture are contacted by said test compound.

38. (Amended) A method of stimulating formation of a biofilm by a population of bacteria, said method comprising at least one of the following steps: adding iron to the growth environment of said bacteria, such that the final concentration of said iron in said growth environment is at least 3 μ M; adding glutamate to the growth environment of said bacteria, such that the final concentration of said glutamate in said growth environment is at least 0.4%; adding citrate to the growth environment of said bacteria, such that the final concentration of said citrate in said growth environment is at least 0.4%; and stimulating expression of a *sad* gene or activity of a *sad* polypeptide.

Please add the following new claims 40 - 54.

40. (Newly added) The method of claim 22, wherein said step comprises inhibiting the synthesis or function of a *sad* polypeptide.

41. (Newly added) The method of claim 22, wherein said step comprises inhibiting protein synthesis in said bacterial cell.

42. (Newly added) The method of claim 22, wherein said step comprises

contacting said bacterial cell with a protease, wherein said contacting is sufficient to prevent said bacterial cell from participating in formation of a biofilm.

43. (Newly added) The method of claim 22, wherein said step comprises limiting the concentration of $\text{Fe}^{2+}/\text{Fe}^{3+}$ in the environment of said bacterial cell, wherein the $\text{Fe}^{2+}/\text{Fe}^{3+}$ concentration in said environment is limited to 0.3 μM or less.

44. (Newly added) The method of claim 22, wherein said step comprises providing a high osmolarity environment to said bacterial cell, wherein said osmolarity of said environment is equivalent to or greater than the osmolarity of a solution containing 0.2 M NaCl or 15% sucrose.

45. (Newly added) The method of claim 22, wherein said step comprises adding mannose to the environment of said bacterial cell, such that the mannose concentration in said environment after the addition of said mannose is at least 15 mM.

46. (Newly added) The method of claim 22, wherein said step comprises adding α -methyl-D-mannoside to the environment of said bacterial cell, such that the α -methyl-D-mannoside concentration in said environment after the addition of said α -methyl-D-mannoside is at least 15 mM.

47. (Newly added) The method of claim 38, wherein said step comprises adding iron to the growth environment of said bacteria, such that the final concentration of said iron in said growth environment is at least 3 μ M.

48. (Newly added) The method of claim 38, wherein said step comprises adding glutamate to the growth environment of said bacteria, such that the final concentration of said glutamate in said growth environment is at least 0.4%.

49. (Newly added) The method of claim 38, wherein said step comprises adding citrate to the growth environment of said bacteria, such that the final concentration of said citrate in said growth environment is at least 0.4%.

50. (Newly added) The method of claim 38, wherein said step comprises stimulating expression of a *sad* gene or activity of a *sad* polypeptide.

51. (Newly added) A method of screening for compounds that modulate biofilm formation, said method comprising:

- a) exposing a bacterial culture to a test compound, such that at least one bacterial cell in said bacterial culture are contacted by said test compound, and
- b) testing said bacterial culture for biofilm formation on an abiotic surface,

wherein a decrease in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound, indicates a compound that inhibits biofilm formation, and an increase in biofilm formation, relative to biofilm formation by a bacterial culture that has not been exposed to said test compound, indicates a compound that stimulates biofilm formation.

52. (Newly added) The method of claim 51, wherein said bacterial culture is a liquid bacterial culture.

53. (Newly added) The method of claim 51, wherein at least 5% of the bacterial cells contacted by the bacterial growth medium in said culture are contacted by said test compound.

54. (Newly added) The method of claim 51, wherein said bacterium is chosen from the group including: *Pseudomonas fluorescens*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Vibrio paramaemolyticus*, *Salmonella typhimurium*, *Streptococcus mutans*, *Enterococcus* species, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis*, *Staphylococcus haemolyticus*, *Staphylococcus warneri*, *Staphylococcus cohnii*, *Staphylococcus saprophyticus*, *Staphylococcus capitis*, and *Staphylococcus lugdunensis*.

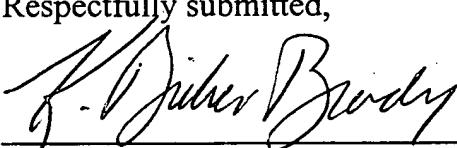
REMARKS

The amendments to the claims are formal in nature and are made to clarify and more particularly state the Applicants' invention. Support for new claims 40-50 is found, for example, on page 5, lines 20-27; page 6, lines 1-8; and page 8, lines 15-24 of the specification. Support for new claims 51-54 is found, for example, on page 3, lines 1-8; page 7, lines 23-27; and page 8, lines 1-14. No new matter is added by these amendments.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: December 20, 2000



Kristina Bieker-Brady

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